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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,776	08/18/2003	Swapan Roy	406-01	3684
39065 7590 01/05/2007 PROTEUS PATENT PRACTICE LLC P.O. BOX 1867 NEW HAVEN, CT 06508			EXAMINER GROSS, CHRISTOPHER M	
			ART UNIT	PAPER NUMBER
			1639	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/05/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/642,776

Applicant(s)

ROY ET AL.

Examiner

Christopher M. Gross

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 13 November 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 19-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/13/2004</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Responsive to communications entered 11/13/2006. Claims 1-36 are pending. Claims 19-36 are withdrawn. Claims 1-18 are examined herein.

#### ***Priority***

This application claims benefit of 60/403,747 08/16/2002.

#### ***Election/Restrictions***

Applicant's election with traverse of group II (claims 10-18) and the species of silica per claim 14 in the reply filed on 11/13/2006 is acknowledged.

During a telephone call with Henry Auer, a further election was made of succinate as the specificity determining ligand ( $\text{HOOC}(\text{CH}_2)_2\text{CO}-$ ) in claim 2 and silica as set forth in claim 5.

Affirmation of this election must be made by applicant in replying to this Office action.

The traversal is on the ground(s) that groups I and III are not drawn to fluorescence-type *methods* and further both groups are directed to articles of manufacture. This is not found persuasive for the following reasons.

While the Examiner concedes that fluorescence is not explicitly stated in the claims, the criteria for restriction between products may be based on a *different mode of operation*. Regardless, the specificity determining substrate as set forth in groups I and II additionally have different designs as well, in that the specificity determining substrate of groups I and II is placed in a chromatography column, whereas the microarray of group III is not.

In the interest of compact prosecution, however, groups I and II are hereby rejoined.

Claims 19-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/13/2006.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation 'a predetermined minimum distance' yet the specification does not provide a clear definition as to the meaning of what constitutes predetermined.

Moreover, it is noted that paragraph 0081 of the specification indicates a minimum distance as, for example greater than about 4, however no units are given.

As such, the metes and bounds of claim 1 and claims dependent thereof are deemed indefinite.

Claims 6 and 15 each recite the limitation 'a predetermined maximum content' yet the specification lacks a clear definition as to the meaning of predetermined.

As such the metes and bounds of claims 6 and 15 are deemed indefinite.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6,10-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Keyes (US Patent 4,714,676).

The claimed invention is drawn to a specificity-determining substrate that forms a complex with a protein molecule in a homogenous fashion, wherein the specificity-determining substrate comprises a specificity-determining ligand bound to a support, wherein optionally the substrate further comprises a spacer bound between the ligand and the support, wherein the spatial separation between adjacent ligand groups is greater than a predetermined minimum distance, and provided that the substrate is other than a crosslinked chitosan bearing a diethylamino or diethylaminoethyl ligand.

Claims 2-6, 10-15 represent variations thereof.

Keyes teach, throughout the document and especially column 8, lines 39-60 , a composite of a succinylated protein bound to a ceramic oxide, and absent evidence to the contrary the separation between adjacent ligand groups is greater than a predetermined minimum distance, thus reading on claims 1, 4 and 13 of the instant application. It is noted that the spacer molecule is "optional."

The succinyl groups of Keyes read on claims 2 (elected species) and 3. The protein of Keyes reads on the protein of claims 10-13.

Keyes et al teach silica as an alternative support in column 5 line 66, reading on claims 5 (elected species) and claim 14 (elected species).

Claims 1-6,8-9,10-15,17-18 rejected under 35 U.S.C. 102(b) as being anticipated by Comb et al (US Patent 5,843,247).

Comb et al teach, throughout the document and especially figure 28 a chitin binding column for the purification of expressed proteins fused with an intein and chitin binding domain and absent evidence to the contrary the separation between adjacent ligand groups is greater than a predetermined minimum distance, thus reading on claims 1, 4 and 13 of the instant application. It is noted that the spacer molecule is "optional."

The fusion protein of Comb et al reads on the protein of claim 10.

Comb et al teach in columns 57-58 preparations of two types of substrates, including chitosan bound to sepharose and chitin itself. The former support reads on the oligosaccharide of claim 2. Therein the fusion protein of Comb et al also reads on the protein of claim 11.

For claim 3: Comb et al teach in column 57, line 17 sepharose is modified by 1,4-butanediol diglycidioxy ether which reads on claim 3 when the specificity determining ligand comprises  $R_1-O-R_5$  and  $R_1$  and  $R_5$  represent a normal aliphatic moiety. Therein the fusion protein of Combe et al also reads on the protein of claim 12.

For claims 5 and 14, the substrate of Comb et al is represents a bead.

For claim 8 and 17, the sepharose of Comb et al comprises a polysaccharide.

For claim 9 and 18, the substrate(s) of Comb et al comprises chitosan (e.g. see column 57, line 34).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Comb et al** (US Patent 5834247) in view of **Margel** (US Patent 4732811)

**Comb et al** is relied on as above.

Comb et al do not explicitly teach the solids content of the support being less than 8% (w/v) as set forth in claims 7 and 16.

**Margel** teaches, throughout the document and especially the abstract, the preparation of polyaldehyde beads. In particular, Margel teaches in column 4, line 34 a solution containing 0.8 grams agarose in 20 ml aqueous solution, or 4 % (w/v) as part of the protocol in preparing said polyaldehyde beads.

It would have been *prima facie* obvious for one of ordinary skill in the art, at the time the claimed invention was made, to prepare an 4 % w/v slurry as part of the protocol in preparing polyaldehyde beads per Margel comprising the chitin material of Comb et al.

One of ordinary skill in the art would have been motivated to apply the polyaldehyde of Margel toward the chitin material of Comb et al because it is useful in various applications including affinity chromatography, hyperperfusion, etc, as noted by Margel in the abstract.

Furthermore, absent evidence to the contrary, given the 'about' language in paragraph 0061 of the specification concerning 'the solids content of the support' limitation set forth in claims 7 and 16, it does not appear said limitation represents a critical parameter for the functioning of the claimed invention (see MPEP 2173 II) And according to *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

One of ordinary skill could apply the polyaldehyde of Margel toward the chitin material of Comb et al with a reasonable expectation of success since the polyaldehyde of Margel has been applied in chromatography. Therefore it is not unreasonable to



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apply the polyaldehyde of Margel toward the chitin material of Comb et al because chitin lies within the scope of chromatography media. Additionally, Margel teach many successful examples.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Gross whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz can be reached on 571 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

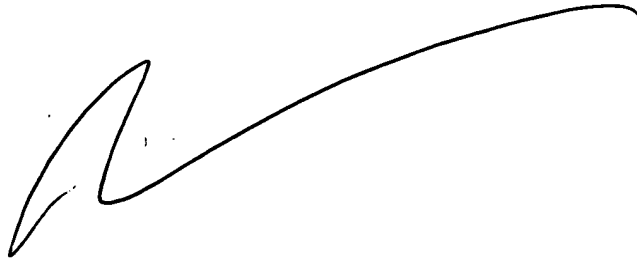
Christopher M Gross  
Examiner  
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**JON EPPERSON  
PRIMARY EXAMINER**

A handwritten signature in black ink, consisting of a large, stylized 'J' followed by a long, sweeping horizontal stroke that curves slightly upwards at the end.